

Application No.: 10/797,367

Amendment Dated: February 11, 2009

Reply to Office Action Mailed: October 31, 2008

**REMARKS**

Upon entry of the accompanying amendment, claims 28, 30-32, 34 and 39-41 will remain pending in the present application. The amendment limits the claims to compositions comprising a delivery vehicle consisting of Tranilast or its analogs in a biodegradable polymer. No new matter is presented.

Entry of the accompanying amendment is earnestly solicited under 37 C.F.R. 1.116, as the amendment further limits the claims and therefore raises no new issues which would require further search or consideration by the Examiner. In the alternative, entry is solicited in an effort to place the claims into better form for consideration on appeal.

**Rejection under 35 U.S.C. §102(b) over Mori et al.**

Claims 14, 21, 24, 25, 28, 31, 32 and 39 stand rejected under 35 U.S.C. §102(b) as anticipated by Mori et al. (U.S. 6,239,177). Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

Mori et al. disclose external preparations containing Tranilast for high percutaneous absorption in the form of an aqueous base, containing a solubilizer for Tranilast, a dispersant, an absorption aid, an adhesive and/or a shape retenting agent and water (abstract).

The presently claimed composition is limited to having a delivery vehicle consisting of only Tranilast in a biodegradable polymer in the form of a film, foam, fibers and filaments. The delivery vehicle has no solubilizer for Tranilast, no adhesive, and no water to form an aqueous base.

Application No.: 10/797,367

Amendment Dated: February 11, 2009

Reply to Office Action Mailed: October 31, 2008

Mori et al. fail to disclose or suggest a delivery vehicle containing only Tranilast in a biodegradable polymer in the form of a film, foam, fibers or filaments.

Withdrawal of the rejection is requested.

**Rejection under 35 U.S.C. 103(a) over Mori et al.**

Claims 14, 16, 27, 28, 30, and 34 are rejected under 35 U.S.C. 103(a) as obvious over Mori et al. Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

The deficiency of Mori et al. is discussed above and reiterated here. That is, Mori et al. fail to disclose or suggest delivery vehicles consisting of Tranilast or analogs thereof in a biodegradable polymer.

One of skill in the art would not have been motivated to eliminate the solubilizer for Tranilast, dispersant, absorption aid, adhesive and/or a shape retenting agent and water from the Mori et al. compositions.

Withdrawal of the rejection for failure to establish a prima facie case of obviousness is requested.

**Rejection under 35 U.S.C. 103(a) over Mori et al.**  
**in view of Pope et al.**

Claims 14, 22, 23, 40 and 41 are rejected under 35 U.S.C. 103(a) as obvious over Mori et al. in view of Pope et al. (U.S. 5,948,822). Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

Application No.: 10/797,367

Amendment Dated: February 11, 2009

Reply to Office Action Mailed: October 31, 2008

The deficiency of Mori et al. is discussed above and reiterated here. That is, Mori et al. fail to disclose or suggest delivery vehicles consisting of Tranilast or analogs thereof in a biodegradable polymer.

One of skill in the art would not have been motivated to eliminate the solubilizer for Tranilast, dispersant, absorption aid, adhesive and/or a shape retenting agent and water from the Mori et al. compositions.

Pope et al. disclose topically administering a C18 to C26 aliphatic alcohol to a skin lesion in a pharmaceutically acceptable carrier (abstract) for treating or inhibiting the growth of hyperproliferative skin lesions, wherein the carrier may be white petrolatum, isopropyl myristate, lanolin or lanolin alcohols, mineral oil, sorbitan mono-oleate, propylene glycol, cetylstearyl alcohol, which can be combined with a detergent and mixed with water to form a lotion, gel, cream or semi-solid composition (col. 3, lines 41-49).

Pope et al. fail to cure the deficiency of Mori et al.

Withdrawal of the rejection for failure to establish a prima facie case of obviousness is requested.

**Rejections under 35 U.S.C. §102(b)**

Claims 14, 16, 24, 25, 28, 30, 31 and 32 stand rejected under 35 U.S.C. §102(b) as anticipated by Isaji et al. Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

Isaji et al. disclose compositions containing Tranilast in the form of powders, granules, fine granules, dry syrups, tablets, capsules, ointments, injections and eye drops (col. 4, lines 30-33). Isaji et al. fail to disclose

Application No.: 10/797,367

Amendment Dated: February 11, 2009

Reply to Office Action Mailed: October 31, 2008

compositions containing a delivery vehicle consisting of Tranilast or its analogs in a biodegradable polymer in a form selected from the group consisting of film, foam, fibers, and filaments.

Withdrawal of the rejection is requested.

Rejection under 35 U.S.C. 103(a) over Isaji et al.

in view of Akhtar et al.

Claims 14, 22, 23, 28, 40 and 41 are rejected under 35 U.S.C. 103(a) as obvious over Isaji et al. in view of Akhtar et al. (U.S. 5,432,163). Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

The deficiencies of Isaji et al. are discussed above and reiterated herein.

Akhtar et al. disclose anti-proliferative and anti-inflammatory compounds which are derivatives of pentose monosaccharides (title). The Akhtar et al. compounds are disclosed to administered orally, topically, rectally, anterally, internally, by boluses, or parenterally, preferably orally, in forms such as granules, powders, coated tablets, microcapsules, suppositories, syrups, elixirs, suspensions, emulsions, drops or injectable solutions (col. 8, lines 40-47). Akhtar et al. fail to disclose or suggest incorporating their new compounds in delivery vehicles consisting of Tranilast or its analogs in a biodegradable polymer in a form selected from the group consisting of film, foam, fibers, and filaments and therefore cannot cure the deficiency of Isaji et al.

Withdrawal of the rejection for failure to establish a prima facie case of obviousness is requested.

Application No.: 10/797,367

Amendment Dated: February 11, 2009

Reply to Office Action Mailed: October 31, 2008

**Rejection under 35 U.S.C. 101 for provisional double patenting over copending application no. 10/714,719**

Claims 14-19, 21-25, 27-37 and 39-41 are provisionally rejected under 35 U.S.C. 103(a) for statutory double patenting over claims 14-41 of copending application no. 10/714,719.

Reconsideration of the double patenting rejection is requested in view of the accompanying amendment presented herein.

**Rejection for provisional nonstatutory double patenting over copending application no. 10/780,452 in view of Chandrasekar et al. Or Miyazawa et al.**

Claims 14-19, 21-25, 27-37 and 39-41 are provisionally rejected for nonstatutory double patenting over claims 14-19, 21-24 and 27-41 of copending application no. 10/780,452, in view of Chandrasekar et al. ("Platelets and Restenosis") or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat").

Reconsideration of the double patenting rejection is requested in view of the accompanying amendment herein.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478(14788).

Application No.: 10/797,367

Amendment Dated: February 11, 2009

Reply to Office Action Mailed: October 31, 2008

In view of the foregoing, it is respectfully submitted that the present claims are in condition for allowance. Prompt notification of allowance is respectfully solicited.

If the Examiner has any questions or wishes to discuss this application, the Examiner is invited to contact the undersigned representative at the number set forth below.

Respectfully submitted,



Michael J. Mlotkowski

Reg. No. 33,020

Attorney for Applicants

703-584-3270

DATED: February 11, 2009

CORRESPONDENCE ADDRESS:

Roberts Mlotkowski Safran & Cole  
P.O. Box 10064  
McLean, VA 22102